

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE**

A. 510(k) Number: k043512

B. Purpose For Submission:

Premarket Notification 510(k) of intention to manufacture and market the EasyGluco Blood Glucose Monitoring System

C. Analyte: Whole Blood Glucose

D. Type of Test: Quantitative, utilizing Glucose Oxidase technology.

E. Applicant: American HealthCare, Inc.

F. Proprietary and Established Names: EasyGluco Blood Glucose Monitoring System

G. Regulatory Information:

1. Regulation section: 21 CFR §862.1345, Glucose test system.
2. Classification: Class II, I
3. Product Code: NBW, CGA, JJX
4. Panel: 75 Chemistry

H. Intended Use:

1. Intended use(s):

See indication for use below.

2. Indication(s) for use:

The EASYGLUCO Blood Glucose Monitoring System is used for the quantitative measurement of glucose levels in whole blood as an aid in monitoring the effectiveness of diabetes management in the home and in clinical settings. EASYGLUCO Blood Glucose Monitoring System is for testing outside the body (in vitro diagnostic use only). Testing sites include the traditional fingertip testing along with alternate site testing on the arm, palm, thigh and calf.

3. Special condition for use statement(s):

Provides plasma equivalent results.

4. Special instrument Requirements:

Not Applicable

I. Device Description:

The EASYGLUCO System consists of the EASYGLUCO meter, EASYGLUCO Test Strips, Auto-Lancet Device, Infopia Check Strip and Greenlan Lancets, and Control Solution. Control Solution is sold separately from the kit. Controls previously cleared under K031501.

J. Substantial Equivalence Information:

1. Predicate device name(s):

LifeScan, Inc. OneTouch® Ultra®

2. Predicate K number(s): K024194

3. Comparison with Predicate:

The US Diagnostics, Inc. EASYGLUCO Blood Glucose Monitoring System is substantially equivalent to the LifeScan, Inc. OneTouch Ultra Blood Glucose Monitoring System previously cleared under (k024194). The table below lists the similarities and differences between the Predicate and Proposed device.

This EASYGLUCO Blood Glucose Monitoring System is the exact same blood glucose meter previously cleared under k031501. The difference between the previously cleared EASYGLUCO Diabetes Monitoring System and this meter is a change in the meter case, the addition of the EasyGluco diabetes management software, and the addition of Alternate-Site testing of the arm, palm, thigh, and calf. A Software Validation Report, Users Guide, Alternate-Site raw data, and Human Factor Studies are included in this submission.

Substantial Equivalence Comparison

Similarities

	EasyGluco	One Touch® Ultra®
Detection method	Amperometry: current is generated by oxidation of reduced mediator	Amperometry
Enzyme	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Mediator	Potassium ferricyanide	Potassium ferricyanide
Electrode	Carbon electrode	Carbon electrode

The other ingredients of the test strip, such as enzyme stabilizer, buffer and binder are different.

Differences

	EasyGluco	One Touch® Ultra®
Test range	10 – 600 mg/dL	20 – 600 mg/dL
Hematocrit Range	30 – 55%	30 – 55%
Test Time	9 seconds	5 seconds
Sample Volume	3 µL	1 µL
Temperature & Humidity range	50 - 95° F 10 - 35° C 10 – 90 %	43 - 111° F 6 – 44 ° C 10 – 90%
Open use time	3 months	3 months
Coding	Button (C1 –C40)	Button (C1 – C49)
Memory capability	From 7 to 90-day average and 200 tests in the memory	14-day average and last 150 tests in the memory
Power	3V Li battery (CR2032)	3V Li battery (CR2032)
Battery life	Running 5,000 test	Running 1,000 test
Size: LxWxH (mm)	56x20x76	57x21x79
Weight	45g (with battery)	42g (with battery)
Warranty	Lifetime	3 years
Software	EasyGluco diabetes management software	IN TOUCH® diabetes management software

K. Standard/Guidance Document Referenced (if applicable):

1. National Committee for Clinical Laboratory Standards. *Point-Care Blood Glucose Testing in Acute and Chronic care Facilities; Approved Guideline*, 2nd Edition. NCCLS Document C30-A2 (ISBN1-56238-471-6).
2. National Committee for Clinical Laboratory Standards. *Statistical Quality Control for Quantitative Measurements; Principle and Definitions; Approved Guideline*, 2nd Edition. NCCLS Document C24-A2 (ISBN1-56238-371-X). 1999
3. National Committee for Clinical Laboratory Standards. *Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline*. NCCLS Document EP10-A (ISBN1-56238-348-5). 1998
4. National Committee for Clinical Laboratory Standards. *Evaluation of Matrix Effects; Approved Guideline*, NCCLS Document EP14-A (ISBN1-56238-434-1).
5. National Committee for Clinical Laboratory Standards. *Estimation of Total analytical Error for Clinical Laboratory Methods; Proposed Guideline*. NCCLS Document EP21-P (ISBN1-56238-456-2).
6. National Committee for Clinical Laboratory Standards. *User Demonstration of performance for Precision and Accuracy; Approved Guideline*. NCCLS Document EP15-A (ISBN1-56238-451-1).

7. National Committee for Clinical Laboratory Standards. *Interference Testing in Clinical Chemistry; Proposed Guideline*. NCCLS Document EP7-P (ISSN 0273-3099).
8. National Committee for Clinical Laboratory Standards. *Evaluation of the Linearity of Quantitative Analytical Methods; Proposed Guideline*, 2nd Edition. NCCLS Document EP6-P2 (ISBN1-56238-446-5).
9. National Committee for Clinical Laboratory Standards. *Evaluation of Performance of Clinical Chemistry Devices; Approved Guideline*. NCCLS Document EP5-A (ISBN1-56238-368-X).
10. Clinical Chemistry, 2nd Edition
11. MERCK INDEX, 11th Edition.
Korea Pharmacopeia, 5th Edition.

L. Test Principle:

The Test Principle used by this device is electrochemical biosensor technology using glucose Oxidase. The strip uses the enzyme glucose Oxidase to produce a current that will stimulate a chemical reaction. This reaction is measured by the Meter and displayed as a blood glucose result.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
 - a. *Precision/Reproducibility:*

The sponsor indicated precision studies were assessed by taking 4mL of blood that was treated with EDTA drawn in a vacuum tube. Glucose was added to the 4 mL of blood to generate 5 different levels of glucose concentration for the test. Each of the samples was measured 5 times for precision. Below are the Glucose Concentration Ranges for each level that were measured.

Level	Glucose Conc. range
1	30 ~ 50 mg/dL
2	51 ~ 110 mg/dL
3	111 ~ 150 mg/dL
4	151 ~ 250 mg/dL
5	251 ~ 400 mg/dL

Day-to-Day precision also known as Between Day Precision

The sponsor prepared three control solutions of Low, Normal and High. Each of the controls was measured twice a day, once in the morning and once in the afternoon for a month.

Table 1 (below) shows a summary of the Within-Run Precision and the Day-to-Day Precision Tests.

Table 1: Summary of Test Results

Control Samples	No. of Assay	Within-Run Precision		
		Mean	SD	CV
		(mg/dL)	(mg/dL)	(%)
Level 1	5	47.2	1.6	<u>3.5</u>
Level 2	5	94.2	2.3	<u>2.4</u>
Level 3	5	131	4.5	<u>3.4</u>
Level 4	5	221	6.0	<u>2.7</u>
Level 5	5	339.8	7.4	<u>2.2</u>

Control Samples	No. of Assay	Day-to-Day Precision		
		Mean	SD	CV
		(mg/dL)	(mg/dL)	(%)
Low	80	74.2	2.8	<u>3.7</u>
Normal	80	128.8	6.2	<u>4.8</u>
High	80	252.9	9.9	<u>3.9</u>

The study showed variability from strip to strip in blood tests of 3.5% or less and from day to day-in control tests of 4.8% or less.

b. Linearity/assay reportable range:

Test Procedure (Dilution Schemes)

The NCCLS recommends dilution schemes to estimate the linearity of the Quantitative Analytical Method.

According to the NCCLS EP6-P2 protocol, a blood sample of 25 mL was taken, treated with the EDTA in a vacuum tube, and let set for a day. Two glucose concentrations of 10 mL (high and low concentrations) were prepared. As a measuring tool, nine glucose concentrations were prepared using the following dilution schemes (see Table 5).

Table 5: Levels of Dilution Schemes

S=9 Samples	
Level 1(Low, L)	L
Level 2	$0.875L + 0.125H$
Level 3	$0.750L + 0.250H$
Level 4	$0.625L + 0.375H$
Level 5	$0.500L + 0.500H$
Level 6	$0.375L + 0.625H$
Level 7	$0.250L + 0.750H$
Level 8	$0.125L + 0.875H$
Level 9(High, H)	H

The meter used in this test can display below 10 mg/dL over 600 mg/dL for checking linear range.

Each of the glucose levels was measured 5 times to test for precision.

In order to evaluate the straight line for the Sensory Strip that was used, the following formula was used:

$$1^{\text{st order}} \text{ polynomial, } y = ax + b, \quad 2^{\text{nd order}} \text{ polynomial, } y = aX^2 + bX + c$$

All dilution schemes start with a high and low concentration of samples in which the concentrations meet or exceed the range of interest. For the test, the highest and lowest glucose concentration used was 630mg/dL and 7mg/dL. If a strip sensor has an ideal linearity ($r^2=1$) from Lowest to highest concentration, the ideal concentration of level 2 mixed with 0.875L and 0.125H volume ratio is a 99mg/dL $[(0.875*37.4 + 0.125*530.2)/(0.875+0.125)]$.

Table 6. below, shows a summary of the nine dilutions that were measured five times for precision.

Table 6: Test Result Summary

Dilution	Rep1	Rep2	Rep3	Rep4	Rep5	Mean
1	7	7	8	7	9	<u>7.6</u>
2	90	90	84	88	88	<u>88</u>
3	156	158	158	158	156	<u>157.2</u>
4	240	240	238	238	234	<u>238</u>
5	307	306	300	298	305	<u>303.2</u>
6	405	402	397	392	398	<u>398.8</u>
7	467	468	468	475	470	<u>469.6</u>
8	542	540	550	550	552	<u>546.8</u>
9	630	625	622	620	630	<u>625.4</u>

The dilution number at Table 6 and Figure 1 represents the Level number at Table 5.

Figure 1: Glucose Linearity Study (Dilution 1-9)

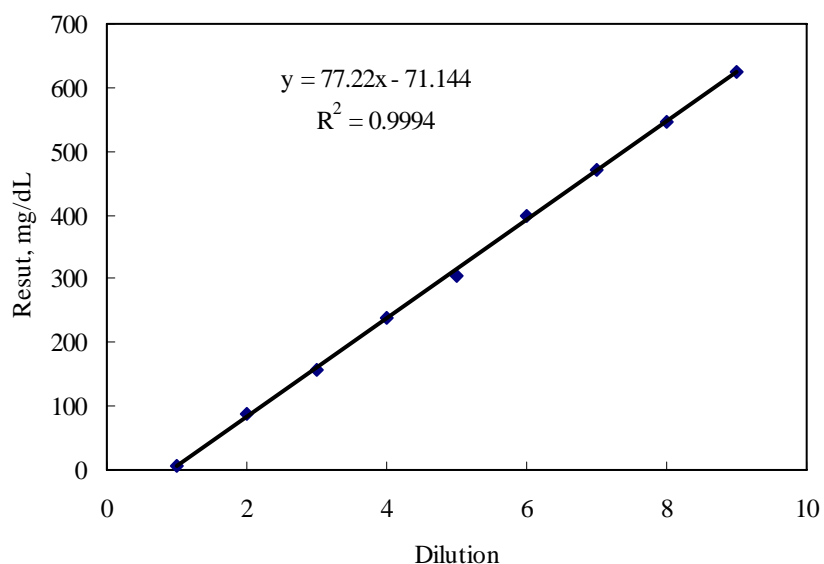


Table 7: The Polynomial Evaluation of Linearity

Dilution	Actual Mean	Predicted 1st order	Predicted 2nd order	Difference
1	<u>7.6</u>	6.1	8.7	-2.7
2	<u>88</u>	83.3	84.0	-0.7
3	<u>157.2</u>	160.5	159.8	0.8
4	<u>238</u>	237.7	236.1	1.6

Dilution	Actual Mean	Predicted 1st order	Predicted 2nd order	Difference
5	<u>303.2</u>	315.0	313.1	1.9
6	<u>398.8</u>	392.2	390.6	1.6
7	<u>469.6</u>	469.4	468.6	0.8
8	<u>546.8</u>	546.6	547.3	-0.7
9	<u>625.4</u>	623.8	626.5	-2.7

It has been determined that the polynomial evaluation of linearity assumes that the data set is not linear. This approach assumes that the data points fall perfectly on a line or curve in the absence of random error. The method consists of two parts. The first part examines whether a nonlinear polynomial fits the data better than a linear one. The second part assesses whether the difference between the best-fitting nonlinear and linear polynomial is less than the amount of allowable bias for the method, which should be predefined.

The nonlinear 2nd fits the data better than a linear one, but the difference is lower than 1.9mg/dL from 7.6mg/dL to 625.4mg/dL. The R² of 1st order regression is a 0.9994

c. Traceability (controls, calibrators, or method):

CAS# (Chemical Abstract Service)
MDL# (MDL, inc. formerly Molecular Design Laboratories)
Glucose # 492615 SigmaUltra MFCD00063989
Traceability referenced to NBS, NIST Standards

d. Detection limit:

10 – 600 mg/dL
0.6 – 33.3 mmol/L
See linearity study above.

e. Analytical specificity:

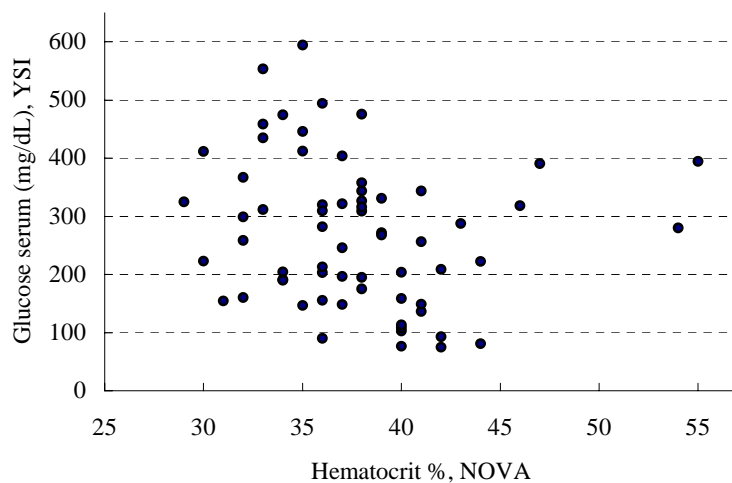
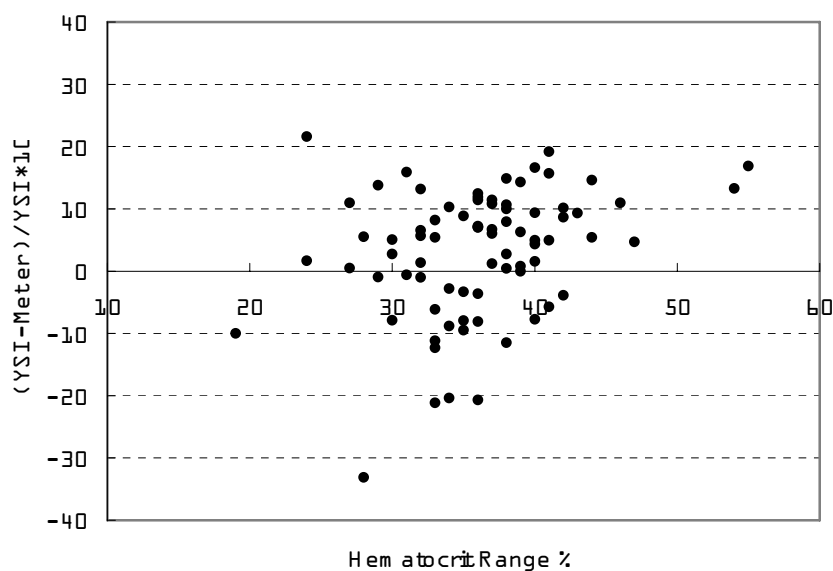
Interference testing was conducted to determine the effect of select endogenous and exogenous substances.

Hematocrit Study

In this study, approximately 2 mL of blood was taken from 64 random diabetic individuals. The blood samples were treated with the EDTA vacuum tube and the glucose concentration was adjusted to 75~590 mg/dL by adding an adequate amount of the phosphate buffer (20mM with pH 7.4) that contains a different level of glucose. In order to adjust the Hematocrit value (30 ~ 55%), a proper volume of the centrifuged plasma (serum) was removed. The Hematocrit level and glucose concentration in the blood was assessed by using the Nova Stat Profile M and the YSI2300 STAT PLUS (respectively).

Test Result of Blood Glucose Range and Samples:

Result of Blood Glucose and Hematocrit Range

Figure 5: Blood glucose conc. Vs Hematocrit %)**Figure 6:** Bias between meter result and the corresponding comparison result.

The % bias of the assay value of the EASYGLUCO™ system is relative to the YSI and does not have a negative or positive correlation to hematocrit level in this experiment. 97% of the data is within +/- 20% bias and 72% lies within +/- 10% in the overall range of glucose and hematocrit.

Summary of Tested Interferences:

Interferences	Mean of Test Results			
	High Test Level(mg/dL)	Low (mg/dL)	High (mg/dL)	Error %
Acetaminophen	<u>20</u>	92.7	102.7	<u>9.7</u>
Bilirubin	<u>40</u>	124.3	137.0	<u>10.2</u>
Gentisic acid	<u>50</u>	128.7	206.0	<u>60.1</u>
Uric acid	<u>20</u>	118.3	153.7	<u>29.9</u>
Levo-Dopa	<u>4</u>	120.0	132.3	<u>10.3</u>
Creatinine	<u>30</u>	108.0	117.7	<u>3.4</u>
Methyl-Dopa	<u>2.5</u>	107.7	120.0	<u>11.4</u>
Tolazamide	<u>5</u>	119.3	126.0	<u>5.6</u>
Dopamine	<u>13</u>	132.7	205.3	<u>54.7</u>
Ascorbate	<u>3</u>	121.7	125.3	<u>3.0</u>
EDTA	<u>640</u>	114.0	117.0	<u>2.6</u>
Glutathione	<u>1</u>	132.3	134.0	<u>1.3</u>
Heparin	<u>1,000</u>	123.0	133.3	<u>8.4</u>
Ibuprofen	<u>40</u>	103.0	107.0	<u>3.9</u>
Salicylic acid	<u>50</u>	121.3	124.7	<u>2.7</u>
Tetracycline	<u>0.4</u>	135.0	137.3	<u>1.7</u>
Tolbutamide	<u>100</u>	98.3	101.7	<u>3.4</u>
Urea	<u>500</u>	114.0	112.3	<u>-1.5</u>
Cholesterol	<u>500</u>	135.3	153.7	<u>13.5</u>
Triglyceride	<u>2,890</u>	122.3	153.7	<u>25.6</u>

According to the sponsor, the list of interfering substances and their high test level in clinical chemistry were referenced to NCCLS Document EP7-P.

All low levels = 0 except: Urea = 3 mg/dL
 Cholesterol = 209 mg/dL
 Triglyceride = 210 mg/dL

It has been determined that reducing substances such as uric acid affect the testing result by falsely increasing values and may activate or deactivate the activity of Glucose Oxidase (GOX), activating GOX makes the test result falsely high.

f. Assay cut-off: Not Applicable

2. Comparison studies:

a. Method comparison with predicate device:

Method comparison to the predicate device was assessed with One hundred sixty subjects with Type 1 or Type 2 diabetes during normally scheduled clinic visits. In the study protocol, both the lay user and a trained technician obtained fingerstick glucose readings on the EASYGLUCO and ONETOUCH ULTRA, as well as alternate site glucose testing on the forearm, part of hand, upper arm, thigh and calf using both the EASYGLUCO and ONETOUCH ULTRA meters.

The readings were taken as close in time as possible. Within 5 minutes, a venous whole blood sample was drawn from alternate sites and centrifuged for making serum. The serum sample was tested on the Hitachi 747. The sponsor indicates that during the comparison studies, alternate sites were vigorously rubbed by the lay user and trained technician before testing, and in some cases a warming pad was used. It has been suggested that the alternate site -to-finger difference may be minimized by rubbing the site before blood collection.

Table1. Summary of test results with finger capillary blood and palm blood obtained by lay user.

		Site	Site 2	Site 3
OneTouch (Palm) vs Hithchi747	Slope: Y- intercept: Linearity:	1.0134 -0.7481 0.9895	0.9978 2.1388 0.99	1.0119 2.5393 0.9823
EasyGluco (Palm) vs Hithchi747	Slope: Y- intercept: Linearity:	0.9862 6.0758 0.9864	1.0028 2.0754 0.9819	1.034 -3.1266 0.9792
EasyGluco (Capillary) vs Hithchi747	Slope: Y- intercept: Linearity:	0.9966 3.9397 0.9914	1.0102 2.57 0.9895	0.9965 3.427 0.9904

		Site	Site 2	Site 3
EasyGluco (Palm) vs EasyGluco (Capillary)	Slope: Y-intercept: Linearity:	0.9876 2.557 0.991	0.9863 0.7271 0.9796	1.0329 -5.7836 0.9798

		Site 1	Site 2	Site 3
OneTouch (Palm) vs Hithchi747	A-region B-region	100% 0%	100% 0%	100% 0%
EasyGluco (Palm) vs Hithchi747	A-region B-region	100% 0%	100% 0%	98 % 2 %
EasyGluco (Capillary) vs Hithchi747	A-region B-region	100% 0%	100% 0%	99 % 2 %
EasyGluco (Palm) vs EasyGluco (Capillary)	A-region B-region	100% 0%	100% 0%	96 % 4 %

Table 2. Summary of test results with finger capillary blood and Arm blood obtained by lay user.

		Site 1	Site 2	Site 3
OneTouch (Arm) vs Hithchi747	Slope: Y-intercept: Linearity:	1.0074 -1.3599 0.9881	0.9744 3.5826 0.9803	1.0083 0.2512 0.9835
EasyGluco (Arm) vs Hithchi747	Slope: Y-intercept: Linearity:	1.0068 -0.6325 0.9912	0.9805 5.3055 0.9824	0.9692 6.766 0.958
EasyGluco (Capillary) vs Hithchi747	Slope: Y-intercept: Linearity:	1.008 -5.0107 0.9914	0.9557 5.8853 0.9822	0.9803 0.0449 0.9873
EasyGluco (Arm) vs EasyGluco (Capillary)	Slope: Y-intercept: Linearity:	0.9944 5.1729 0.991	1.0195 0.4686 0.9876	0.9833 7.7189 0.9895

		Site1	Site 2	Site 3
OneTouch (Arm) vs Hithchi747	A-region B-region	100% 0%	98 % 2 %	94% 6%
EasyGluco (Arm) vs Hithchi747	A-region B-region	100% 0%	100% 0%	100% 0%
EasyGluco (Capillary) vs Hithchi747	A-region B-region	100% 0%	100% 0%	100% 0%
EasyGluco (Arm) vs EasyGluco (Capillary)	A-region B-region	100% 0%	98% 2%	98 % 2 %

Table 3. Summary of test results with finger capillary blood and calf, thigh blood obtained by lay user.

		Site 1	Site 2	Site 3
OneTouch (calf and thigh) vs Hithchi747	Slope: Y- intercept: Linearity:	0.9886 -1.4253 0.9927	0.9952 -3.1461 0.9878	0.9839 -0.5269 0.9899
EasyGluco (calf and thigh) vs Hithchi747	Slope: Y- intercept: Linearity:	0.9765 -0.914 0.9892	1.0147 -6.7943 0.9899	0.9957 -1.5729 0.9872
EasyGluco (Capillary) vs Hithchi747	Slope: Y- intercept: Linearity:	0.9703 3.2533 0.9870	1.0076 -4.0122 0.9902	0.9762 3.6655 0.9859
EasyGluco (calf and thigh) vs EasyGluco (Capillary)	Slope: Y- intercept: Linearity:	1.0002 -2.3942 0.9898	1.0034 -2.1346 0.9926	1.013 -4.0721 0.9876

		Site 1	Site 2	Site 3
OneTouch (calf and thigh) vs Hithchi747	A-region B-region	100% 0%	100% 0%	98 % 2 %
EasyGluco (calf and thigh) vs Hithchi747	A-region B-region	100% 0%	100% 0%	100% 0%
EasyGluco (Capillary) vs Hithchi747	A-region B-region	100% 0%	100% 0%	100% 0%
EasyGluco (Palm) vs EasyGluco (Capillary)	A-region B-region	98% 2%	100% 0%	100% 0%

The comparison test results demonstrated similar results from both meters, with OneTouch at alternate site, EasyGluco at alternate site, and EasyGluco at fingerstick capillary according to the slope, Y-intercept, linearity and error % in Clarke Error Grid region. Test results with EasyGluco at alternative site of hand versus at fingerstick capillary blood, correlation coefficient are 0.9862 ~ 0.9876. Test results with EasyGluco at alternative site of arm versus at fingerstick capillary blood, correlation coefficient are 0.9944 ~ 1.0068. Test results with EasyGluco at alternative site of leg versus at fingerstick capillary blood, correlation coefficient are 0.97656 ~ 1.002. The EasyGluco Blood Monitoring System demonstrates equivalence to the OneTouch Ultra predicate device.

Reference

John M. E: Rapid Changes in Postprandial Blood Glucose Produce Concentration Differences at Finger, Forearm, and Thigh Sampling Sites. Diabetes Care 25: 961-964, 2002

b. Matrix comparison: Not Applicable

3. Clinical studies:

a. *Clinical sensitivity:* Not Applicable

b. *Clinical specificity:* Not Applicable

c. *Other clinical supportive data (when a and b are not applicable):*

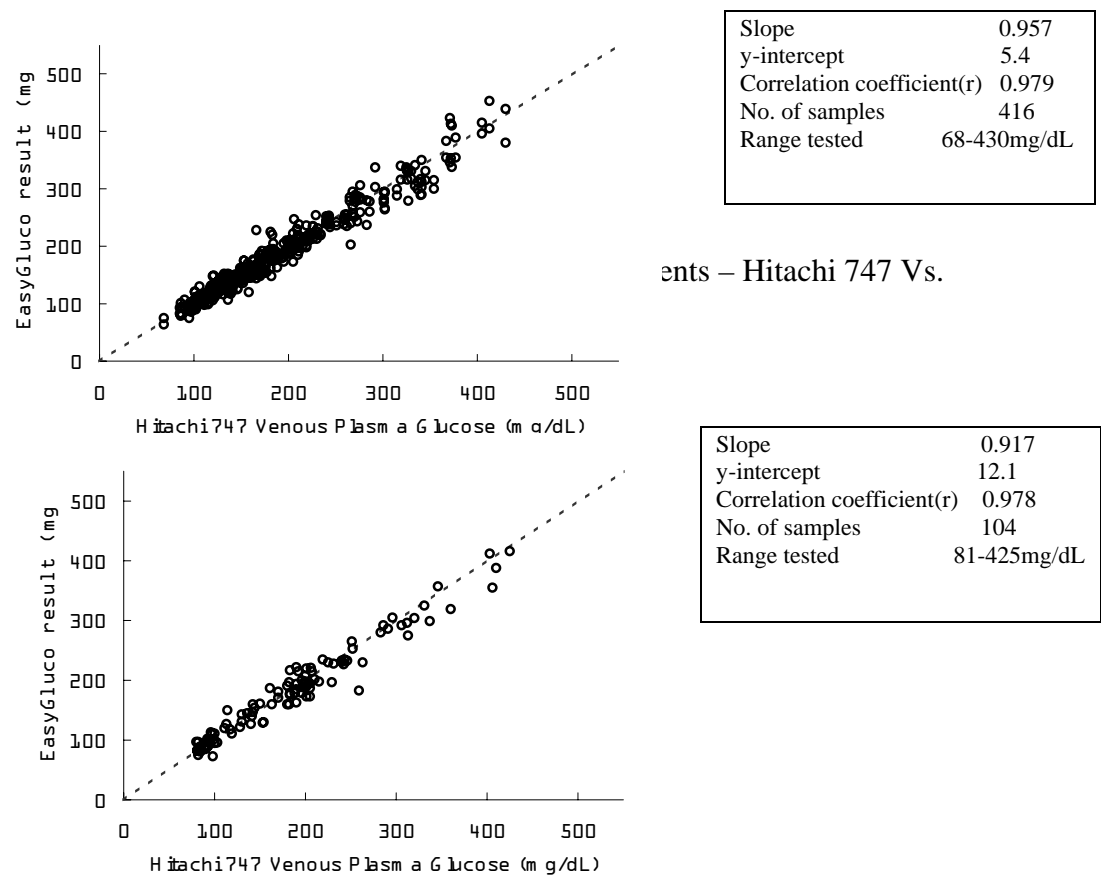
The accuracy of the EASYGLUCO Blood Monitoring System was assessed by comparing blood glucose results obtained by patients with those obtained using the

Hitachi 747, a laboratory instrument. Glucose levels were measured on 416 and 104 fresh capillary blood specimens by 104 diabetic patients and three healthcare professionals at three different clinical centers.

The correlation between Hitachi 747 and EASYGLUCO™ were confirmed in the 416 blood samples with the correlation coefficient $R=0.979$ and the 104 patients with the correlation coefficient $R=0.978$ (Fig. 1 and Fig. 2 respectively). Results indicate that the use of the EASYGLUCO™ generate similar results as the Hitachi 747. The correlation between the EASYGLUCO and Hitachi 747 are within the accuracy standards of NCCLS.

Figure 1: Linear regression of the 416 blood glucose samples with the Hitachi 747 Vs. EASYGLUCO Blood Glucose Monitoring System at the Clinical Centers.

Obtained by Healthcare Professionals in Clinical Centers



4. Clinical cut-off: Not Applicable

5. Expected values/Reference range:

The Range of Expected values was referenced from the Joslin Diabetes Manual.

Expected blood glucose levels for people **without** diabetes:

Time	Range (mg/dL)	Range (mmol/L)
Before Breakfast:	70-105	3.9-5.8
Before lunch or dinner:	70-110	3.9-6.1
1 hour after meals:	Less than 160	Less than 8.9
2 hours after meals:	Less than 120	Less than 6.7
Between 2 and 4 AM:	Greater than 70	Greater than 3.9

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10

O. Conclusion:

The submitted material in this premarket notification is complete and supports a substantial equivalence decision